

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 20-0300V

UNPUBLISHED

DONNA SMITH,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: February 24, 2023

Special Processing Unit (SPU);  
Findings of Fact; Onset; Pre-  
Vaccination History; Scope of Pain  
and Limited Range of Motion;  
Tetanus Diphtheria acellular  
Pertussis (Tdap) Vaccine; Shoulder  
Injury Related to Vaccine  
Administration (SIRVA)

*Leah VaSahnja Durant, Law Offices of Leah V. Durant, PLLC, Washington, DC, for  
Petitioner.*

*Mark Kim Hellie, U.S. Department of Justice, Washington, DC, for Respondent.*

### **FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM<sup>1</sup>**

On March 16, 2020, Donna Smith filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the “Vaccine Act”). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration (“SIRVA”) as a result of a tetanus, diphtheria, and acellular

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<sup>1</sup> Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

pertussis (“Tdap”) vaccine administered on December 28, 2018. Petition at 1. The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”).

For the reasons discussed below, I find that the medical record establishes that the onset of Petitioner’s SIRVA-related pain occurred within 48 hours of vaccination, and that the scope of Petitioner’s pain and reduced range of motion was limited to her right shoulder. However, the evidentiary record does not presently support the conclusion that Petitioner had no pre-vaccination history of right shoulder pain, inflammation, or dysfunction that could explain her post-vaccination symptoms. Petitioner will thus be afforded the opportunity to develop this point, albeit outside of SPU.

## **I. Relevant Procedural History**

As noted above, this case was initiated in March 2020. Despite attempts to informally resolve this case, Petitioner filed a status report in August 2021 indicating that the parties had reached an impasse. ECF No. 26. Petitioner proposed filing a Motion for a Ruling on the Record regarding Onset (“Motion”), followed by Respondent’s combined Rule 4(c) Report and Response to the Motion (“Rule 4/Response.”) *Id.*

Petitioner filed her Motion on September 17, 2021, contending that the onset of her injury occurred within 48 hours of vaccination. ECF No. 29. Respondent filed his Rule 4/Response on October 18, 2021. ECF No. 30. In addition to disputing Petitioner’s allegation of a 48-hour onset, Respondent also argued that Petitioner’s symptoms were not limited to her right shoulder, and that she failed to present preponderant evidence that there was “no prior right shoulder inflammation or dysfunction that would explain her alleged SIRVA” because she had been assessed with calcific tendinitis both before and after vaccination. *Id.* at 8, 10. On October 25, 2021, Petitioner filed a reply maintaining that the onset of her pain occurred within 48 hours of vaccination. ECF No. 31. Further, in addition to arguing that calcific tendinitis was merely suspected, Petitioner asserted that neither this condition nor radiating pain precludes a finding that she suffered a Table SIRVA injury. This matter is now ripe for resolution.

## **II. Issue**

The following issues are contested: whether (1) Petitioner’s first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours; (2) Petitioner’s pain and reduced range of motion were limited to the shoulder in which the intramuscular vaccine was administered; and (3) Petitioner had “[n]o history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings,

and/or diagnostic studies occurring after vaccine injection” as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation (“QAI”) for a Table SIRVA. 42 C.F.R. § 100.3(a) I.C & II.C. (2017) (Tdap vaccination); 42 C.F.R. § 100.3(c)(10)(i)-(iii).

### **III. Authority**

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). I have discussed the factors to be considered in determining whether a petitioner has met their burden in several recent decisions. I fully adopt and hereby incorporate my prior discussion in section III of the following decisions: *Marrow v. Sec’y of Health & Hum. Servs.*, No. 17-1964V, 2020 WL 3639775 (Fed. Cl. Spec. Mstr. June 2, 2020); *Robinson v. Sec’y of Health & Hum. Servs.*, No. 17-1050V, 2020 WL 3729432 (Fed. Cl. Spec. Mstr. June 5, 2020); *Decoursey v. Sec’y of Health & Hum. Servs.*, No.18-870V, 2020 WL 4673228 (Fed. Cl. Spec. Mstr. July 9, 2020).

In sum, a special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of the petitioner’s injury or illness that is contained in a medical record. Section 13(b)(1). Moreover, a special master may find that the first symptom or manifestation of onset of an injury occurred “within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period.” Section 13(b)(2). “Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table.” *Id.*

### **IV. Findings of Fact**

I have reviewed all of the records filed to date. But because my fact ruling focuses on the three issues identified above (onset, situs of injury, and evidence of prior condition), I will only summarize or discuss evidence relevant to the resolution of those issues.

- On March 23, 2016, Petitioner underwent a chest x-ray. The resulting x-ray report notes a “suspicion for right subscapularis calcific tendinitis.” Ex. 10 at 227.
- Petitioner received a Tdap vaccine on December 28, 2018. Ex. 1. It was administered in her right deltoid. *Id.*

- In her supplemental affidavit, signed on August 28, 2020, Petitioner avers that she “immediately felt pain with the injection.” Ex. 11 at 1.
- Petitioner further avers that although she telephoned her physician’s office on January 2, 2019 to request an appointment regarding her shoulder pain, “I was advised to ice my arm if the pain persisted and to call . . . again for a follow up appointment if needed.” Ex. 11 at 1. Petitioner’s phone record indicates that a telephone call was placed to a location in Bremer, Washington on January 2, 2019. Ex. 12 at 1.
- In her supplemental affidavit, Petitioner states that she placed a second call to her primary care provider’s office to request an appointment. Ex. 11 at 1. Although she does not indicate when this call was made, Petitioner avers that she was told that the earliest available appointment was in March 2019. *Id.*
- In his affidavit, signed on August 28, 2020, Petitioner’s husband avers that Petitioner “made several attempts to go see a doctor to get checked out but was frustrated on many times trying not get an appointment.” Ex. 13 at 1.
- On January 16, 2019, Petitioner underwent an initial physical therapy evaluation for lower back and hip pain. Ex. 4 at 41-42. Neither the intake form nor the record documenting this visit does indicate whether Petitioner reported right shoulder pain. See Ex. 4 at 41-42; 65-66.
- Petitioner attended six physical therapy sessions from January 18 through March 14, 2019. Ex. 4 at 43-49. The corresponding records do not indicate whether Petitioner reported right shoulder pain during these visits.
- On March 14, 2019 (2 months, 17 days post-vaccination), Petitioner presented to Dr. Peter M. Lundblad at CHI Franciscan Health for “evaluation of right shoulder pain” that “radiates down her arm into her fingers.” Ex. 6 at 40. The medical record documenting this appointment classify Petitioner’s ailments as a “new problem” that began “when [Petitioner] received her influenza vaccine in her right shoulder in December 2018.” *Id.* Petitioner was assessed with chronic right shoulder pain that “seem[s] to be consistent with rotator cuff tendinopathy.” *Id.* at 44.
- Petitioner was referred to physical therapy on March 15, 2019, for “[r]otator cuff rehab.” Ex. 4 at 34. The referral note indicates that Petitioner “is a 58 y.o. female with calcific tendonitis right shoulder.” *Id.*

- On March 14 and 18, 2019, Petitioner underwent x-rays of her right shoulder and cervical spine. Ex. 6 at 49. The right shoulder x-ray showed mild degenerative changes in Petitioner's shoulder joint and "oval and rounded soft tissue calcifications overlying the superior lateral humeral head" consistent with calcific tendinitis. *Id.* The cervical x-ray showed moderate disc space narrowing. *Id.*
- Petitioner was again examined by Dr. Lundblad on April 12, 2019. Ex. 6 at 45-51. Dr. Lundblad noted that Petitioner "is still very concerned that her tetanus immunization that she had in December triggered the shoulder pain." *Id.* at 46. He further noted that "[Petitioner's] plain films demonstrate exuberant calcific tendinopathy in the region of her external rotators. This is not likely a new process." *Id.* at 50.
- Also on April 12, 2019, Petitioner underwent an x-ray of her right humerus. Ex. 5 at 5. The imaging order indicates that Petitioner had experienced "right upper arm pain following a shot." *Id.* The x-ray revealed calcific bursitis of the subdeltoid bursa without glenohumeral pathology. *Id.*
- Petitioner underwent an MRI of her right humerus and shoulder on April 29, 2019. Ex. 5 at 7-10; Ex. 6 at 89-91. The MRI order reflects that Petitioner had experienced "[r]ight shoulder pain following immunization in December." Ex. 5 at 7. Although the right humerus MRI was negative for any abnormality, the MRI of Petitioner's right shoulder revealed "[c]alcification predominately within the infraspinatus component of the rotator cuff but extending into the posterior supraspinatus component compatible with hydroxyapatite decomposition disease," as well as degenerative joint disease of the acromioclavicular joint and a "small amount of fluid in the subacromial subdeltoid bursa, suggesting bursitis." *Id.*; Ex. 5 at 7, 10; Ex. 6 at 90-91.
- On April 30, 2019, Petitioner presented to Mike Kunish, DPT at Kitsap Physical Therapy for an initial evaluation. Ex. 4 at 10. Petitioner "described symptoms as constant dull aching, fluctuating in intensity, throbbing, and sharp/stabbing." *Id.* The notes documenting this appointment indicate that "the date [Petitioner's] symptoms began was 01/2019 and the mechanism of injury was post inoculation placement into the right shoulder." *Id.* On the patient questionnaire Petitioner described her symptoms as "arm/shoulder pain [that] goes down arm at times to elbow[,] fingers, back shoulder blade." *Id.* at 25.
- Petitioner presented to WestSound Orthopaedics on August 8, 2019, for right shoulder pain "after receiving a tetanus injection in December of 2018." Ex. 5 at

11-14. Petitioner reported that she “initially had tenderness along the deltoid with burning that radiated down the arm.” *Id.* at 11. This note further indicates that Petitioner denie[d] problems with her right shoulder prior to the tetanus injection.” *Id.*

#### A. Onset

The above items of evidence collectively establish that Petitioner’s shoulder pain most likely began within 48 hours of receiving the December 28, 2018 Tdap vaccine. Although Respondent argues that Petitioner’s claim of an immediate onset fails because she “did not report her alleged shoulder injury until she sought treatment . . . 76 days after her vaccination,” Petitioner has presented evidence that she phoned her healthcare provider within *five* days of vaccination. Ex. 12 at 1. Indeed, Respondent acknowledges that Petitioner’s phone record “shows that she called her primary care clinic on January 2, 2019.” Rule 4/Response at 9-10. And this, plus her own testimonial statements, corroborates my onset finding, even in the absence of a direct piece of evidence.

Respondent notes that Petitioner failed to mention her right shoulder symptoms during some intervening physical therapy appointments concerning hip and back pain – the first of which occurred only 19 days post-vaccination. It is certainly reasonable to expect a person suffering from a recent shoulder injury to raise the matter at physical therapy. In a case where there was a much longer gap from vaccination to the first recorded instance of complaints, or other inconsistencies, this omission would be more damning. But in this case, Petitioner clearly began complaining “on the record” of shoulder pain within approximately two and a half months of vaccination, and she consistently attributed her shoulder pain to vaccination. See, e.g., Ex. 6 at 40 (March 14, 2019 medical note indicating that Petitioner’s symptoms began “*when [she] received* her influenza<sup>3</sup> vaccine . . . in December 2018”) (emphasis added); *Id.* at 46 (April 12, 2019 treatment note documenting Petitioner’s “concern[ ] that her tetanus immunization . . . triggered the shoulder pain.”); Ex. 5 at 11 (August 8, 2019 orthopedic record noting that Petitioner experienced shoulder pain “*after receiving* a tetanus injection in December of 2018”) (emphasis added). Furthermore, the affidavits submitted by Petitioner and her husband are consistent with the medical evidence, and I have found no reason not to deem them credible otherwise.

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<sup>3</sup> Reference to an influenza vaccination appears to be an error. This report also indicates that Petitioner presented “with right shoulder pain 3 months, started after Tdap injection into deltoid on right.” Ex. 6 at 44.

*B. Scope of Pain and Limited Range of Motion*

Respondent argues that Petitioner has failed to establish that she suffered a Table injury because her symptoms were not limited to her right shoulder. Rule 4/Response at 10. He asserts that Petitioner “reported to Dr. Lundbald and her physical therapist that her shoulder pain radiated down her arm into her fingers.” *Id.*

I find, however, that (for purposes of the Table SIRVA claim), a preponderance of evidence supports the conclusion that Petitioner’s injury was limited to her right shoulder, even if pain elsewhere in the arm is documented. It is true that Petitioner described radiating symptoms during her first post-vaccination medical and physical therapy appointments, and later noted that she “initially” experienced deltoid tenderness that radiated down her arm. Ex. 6 at 40; Ex. 4 at 25; Ex. 5 at 11. However, Petitioner’s records reveal that these sensations were incidental to her right shoulder pain. See, e.g., Ex. 6 at 44 (March 14, 2019 medical note documenting that Petitioner was assessed with chronic right shoulder pain); *Id.* at 49-50; (April 12, 2019 medical note indicating that Petitioner was assessed with calcific tendonitis of the right shoulder and pain in her right upper arm); Ex. 4 at 10 (April 30, 2019 initial physical therapy note reflecting diagnoses of joint pain, bursitis and “calcific” tendonitis of the shoulder). Moreover, all records indicate that Petitioner’s pain originated from her right shoulder, and that this locus was her primary concern. No records indicate pain radiating *upward* from the fingers. And Petitioner’s post-vaccination treatment focused on her shoulder symptoms. See, e.g., Ex. 4 at 34 (March 15, 2019 referral to physical therapy for rotator cuff rehabilitation).

Accordingly, preponderant evidence establishes that Petitioner’s pain was sufficiently “limited” to her right shoulder for a favorable ruling on this SIRVA element.

*C. Pre-Vaccination History*

Despite Petitioner’s success in satisfying the two QAI criteria previously discussed, it does not at present appear she can satisfy the first criterion for a Table SIRVA, which requires “[n]o history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection.” 42 C.F.R. § 100.3(c)(10)(i).

As noted by Respondent, suspicion for “right subscapularis calcific tendinitis” was documented in a March 2016 x-ray report. Ex. 10 at 227. Although there is a subsequent records gap in which this issue is not discussed, approximately three years later (on April

12, 2019) – and a little less than four months post-vaccination - Petitioner was assessed with “calcific tendonitis of [her] right shoulder” after an x-ray performed one month earlier showed “oval and rounded soft tissue calcifications overlying the superior lateral humeral head.” Ex. 6 at 49-50. A subsequent April 29, 2019 MRI of Petitioner’s right shoulder revealed “[c]alcification predominately within the infraspinatus component of the rotator cuff.” Ex. 5 at 10; Ex. 6 at 90.

In response, Petitioner first argues that *subscapularis* calcific tendinitis was merely suspected in 2016. and “there is no evidence that [this condition] remained for years after her diagnosis.” Reply at 2. Petitioner then asserts that because “[n]one of [her] post-vaccination diagnoses were for right subscapularis calcific tendinitis but instead for issues with the superior lateral humeral head and the subdeltoid regions . . . [R]espondent’s attempt to use a prior suspected diagnosis to explain [P]etitioner’s SIRVA injury fails.” Reply at 2. While this may be a reasonable distinction, on April 12, 2019, Dr. Lundblad opined that Petitioner’s “calcific tendinopathy in the region of her external rotators” was “not likely a new process.” Ex. 6 at 50. And although it is unclear whether Dr. Lundblad believed that this diagnosis stemmed back to 2016 (or arose at some point thereafter), Petitioner has failed to preponderantly prove that calcific tendinitis did not pre-date her December 2018 vaccination and that it does not explain her right shoulder pain.

Based on the foregoing, Petitioner cannot satisfy the first QAI criterion for a Table SIRVA – or, at the very least, the matter is reasonably-disputed, and will require factual development before it can be determined with certainty whether this Table element can be met.

#### **V. Potential for Off-Table Claim**

A petitioner’s failure to establish a Table injury does not necessarily constitute the end of the case, because he or she might well be able to establish a non-Table claim for either causation-in-fact or significant aggravation. See *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005); *W.C. v. Sec’y of Health & Human Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (citing *Loving v. Sec’y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009)). Here, determining if this “prior cause” QAI has been met will require further review, and most likely the retention of experts, which I am not inclined to authorize in the SPU. Moreover, this case has already been pending in the SPU for almost three years – meaning it is inadvisable to allow it to stay in SPU any longer.

### **Conclusion**

Pursuant to Vaccine Rule 3(d), I will issue a separate order reassigning this case randomly to a Special Master.

**IT IS SO ORDERED.**

**s/Brian H. Corcoran**

Brian H. Corcoran  
Chief Special Master